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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,747

11/21/2005

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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

07/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,747	Applicant(s) NISHIBAYASHI ET AL.	
	Examiner MARCOS SZNAIDMAN	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9 pages / 11/21/05, 02/21/06 and 03/14/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on March 31, 2008.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1, 2 and 4) in the reply filed on March 31, 2008 is acknowledged. The traversal is on the ground(s) that Umehara et. al. (Drug Metabolism and Disposition (2000) 28:1417-1424, cited by applicant) does not teach or suggest a preparation containing olanexidine and an excipient, such as polyoxyethylene higher alkyl ethers, alcohols, etc. This is not found persuasive, the fact is that a composition containing olanexidine is obvious from the prior art, and for that reason it can not be a special technical feature under PCT rule 13.2. Since there is no special technical feature, the inventions of Groups I-XII can be restricted because they do not relate to a single general inventive concept. This is completely unrelated to whether the claims are patentable or not.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1-25 are currently pending and are the subject of this office action.

Claims 3, and 5-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic

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or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 31, 2008.

Claims 1, 2 and 4 are presently under examination.

Priority

The present application is a 371 of PCT/JP04/07436 filed on 05/25/2004.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et. al. (US 5,376,686, cited by applicant).

Claims 1-2 recite a composition containing olanexidine acid addition salt, and a polyoxyethylene-based nonionic surfactant: polyoxyethylene higher alkyl ether (group I).

For claims 1 and 2, Ishikawa teaches a composition containing monobiguanidine of example 1 (olanexidine hydrochloric salt) with a polyoxyethylene-based nonionic

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surfactant: polyoxyethylene phenyl ether (see columns 23 and 24: Prescriptions 1 and 2).

Ishikawa does not teach the polyoxyethylene-based nonionic surfactant: polyoxyethylene higher alkyl ether. However, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to replace the surfactant polyoxyethylene phenyl ether with polyoxyethylene higher alkyl ether, since both are polyoxyethylene-based nonionic surfactants with similar properties, thus resulting in the practice of claims 1-2 with a reasonable expectation of success.

Claim 4, further limits claim 1, wherein the amount of olanexidine is 0.05 to 5.0% W/V% and the polyoxyethylene-based nonionic surfactant is 0.1 to 10.0 W/V%.

For claim 4, Ishikawa further teaches concentrations of olanexidine between 0.5 and 5% W/V and concentrations of nonionic surface active agent of 0.375 to 3.75 % W/V.

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to use the concentrations of olanexidine and nonionic surfactant taught by Ishikawa, thus resulting in the practice of claim 4 with a reasonable expectation of success

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1611
July 9, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615